

### **REMARKS/ARGUMENTS**

1. Claims 1-16 were previously pending. Claims 3-13 were withdrawn from consideration by the Examiner, as being drawn to a non-elected invention. Claims 1 and 2 had been canceled. Claims 14 and 15 have been allowed. Claim 16 has been rejected.

Applicants hereby request further examination and reconsideration of the application, in view of the remarks.

2.     • Claims 16 has been rejected under 35 U.S.C. 112, first paragraph.

#### ***Rejections of Claim 16 under 35 U.S.C. 112, first paragraph***

3. The Examiner has rejected Claim 16 under 35 U.S.C. 112, first paragraph, "as failing to comply with the written description requirement. The claim contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention." The Examiner states that "Claim 16 is dependent ultimately upon claim 14, the claim is drawn to a variant strain of *Eimeria maxima* wherein said variant corresponds in characteristics to the strain *E. maxima*-I

(ATCC number PTA-4959) as set forth in claim 15 wherein: immunization with said variant strain or *E. maxima*-I (ATCC number PTA-4959) protects against challenge with said variant strain or *E. maxima*-I (ATCC number PTA-4959) but does not protect against challenge with *E. maxima*-GLP, an indication that *E. maxima*-I (ATCC number PTA-4959) has no detectable immunological cross reactivity with *E. maxima*-GLP (Page 3). The Examiner asserts that the written description sets forth the strain *E. maxima*-I ATCC number PTA-4959 and that therefore the written description is not commensurate in scope with the claim drawn to a variant strain of *E. maxima* wherein said variant corresponds in characteristics to the strain *E. maxima*-I (ATCC number PTA-4959). Thus, the resulting variant strain could result in a strain not taught and enabled by the specification (Page 4). The Examiner further asserts that with the exception of deposited *E. maxima*-I variant strain identified as ATCC number PTA-4959, the skilled artisan cannot envision the variant strain.

Applicant respectfully traverses the rejection. Claim 15 recites the distinguishing characteristics by which the variants are distinctly recognizable or known, *i.e.*, those characteristics which are commonly shared by *E. maxima*-I and the variant. Claim 15 recites, "[T]he variant strain *E. maxima*-I (ATCC number PTA-4959) of Claim 14 which is further identified by the characteristic wherein: immunization with *E. maxima*-I (ATCC number PTA-4959) protects against challenge with *E. maxima*-I (ATCC number PTA-4959) but does not protect against challenge with the Guelph strain of *E. maxima*, designated *E. maxima*-GLP, an indication that *E. maxima*-I (ATCC number PTA-4959) has no detectable immunological cross reactivity with *E. maxima*-GLP. Claim 16 recites, "A variant strain of *Eimeria maxima* wherein said variant strain corresponds in characteristics to the strain *E. maxima*-I (ATCC number PTA-4959) as set forth in Claim

15 wherein: immunization with said variant strain or *E. maxima*-I (ATCC number PTA-4959) protects against challenge with said variant strain or *E. maxima*-I (ATCC number PTA-4959), but does not protect against challenge with *E. maxima*-GLP, an indication that said variant strain has no detectable immunological cross reactivity with *E. maxima*-GLP.

Given the guidance of the specification and the claims, one of skill in the art would know whether another variant strain of *E. maxima* corresponded in characteristics with *E. maxima*-I. Undue experimentation would not be required. For vaccine purposes, another strain having the same characteristics as *E. maxima*-I (ATCC number PTA-4959) could be used in a vaccine in the same way as *E. maxima*-I (ATCC number PTA-4959). The Examiner appears to be indicating that a variant strain of parasite must be described by nucleic acid structure rather than by characteristics (Pages 6-7). Cell lines, and here a parasitic strain, are described by their identifying characteristics and cannot be described by their DNA sequence.

In view of the amendment and above remarks, it is respectfully requested that the rejection under 35 U.S.C. paragraph 112, first paragraph, written description, be withdrawn.

4. The Examiner has rejected Claim 16 under 35 U.S.C. 112, first paragraph, "as failing to comply with the written description requirement. This is a new matter rejection." The Examiner asserts that neither the specification nor originally presented claims provides support for a variant strain of *Eimeria maxima* wherein said variant corresponds in characteristics to the strain *E. maxima*-I (ATCC number PTA-4959).

Appl. No. 09/838,382  
Amendment dated September 2, 2004  
Reply to Office action of June 15, 2004

Applicant respectfully traverses the rejection. No new matter has been introduced by amendment. Support for Claim 16 is found in original Claim 2 and is therefore proper. Original Claim 2 recites, "[A]n immunovariant strain of *Eimeria maxima* that corresponds in characteristics to the strain *E. maxima*-I." It is stated in the MPEP (MPEP 2163.06 III) that the "claims as filed in the original specification are part of the disclosure and therefore, if an application as originally filed contains a claim disclosing material not disclosed in the remainder of the specification, the applicant may amend the specification to include the claimed subject matter."

In view of the amendment and above remarks, it is respectfully requested that the rejection under 35 U.S.C. paragraph 112, first paragraph, written description, new matter, be withdrawn.

#### CONCLUSION

The office action was mailed on June 15, 2004, and this response is submitted within the three month period for reply, therefore no extension of time is required and no fee is due. Please charge any additional fees which may be required at any time during prosecution of the instant application to deposit account 50-2134.

Applicants appreciate the Examiner's allowance of Claims 7 and 8. It is believed that all of the claims and the specification are in condition for allowance. Accordingly, it is respectfully requested that the rejections be withdrawn and that the instant application

Appl. No. 09/838,382  
Amendment dated September 2, 2004  
Reply to Office action of June 15, 2004

be allowed to issue. If any issues remain to be resolved, the Examiner is invited to telephone the undersigned at the number below.

Respectfully submitted,

September 2, 2004      Evelyn M. Rabin  
Date

Evelyn M. Rabin, Ph.D., Patent Advisor

Registration No. 44,480

USDA-ARS-OTT

5601 Sunnyside Ave., Rm. 4-1186

Beltsville, Maryland 20705-5131

Telephone: (301) 504-4781

Fax: (301) 504-5060